

BS



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,789	02/12/2002	Todd R. Golub	WIBL-P02-518	8072

28120 7590 04/15/2005

FISH & NEAVE IP GROUP
ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,789

Applicant(s)

GOLUB ET AL.

Examiner

Marjorie A. Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 65, 66 and 71 is/are pending in the application.
- 4a) Of the above claim(s) 65 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/30/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

All rejections and objections not reiterated below are hereby withdrawn.

Election/Restrictions

Claims 65-66 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 1/20/04.

An action on the merits of elected claims 1-14 and 71, as they read on the elected species, follows.

Information Disclosure Statement

The information disclosure statement filed 3/30/05 has been considered in full. Reference CC by Golub et al. was previously cited on a PTO Form 892 mailed with the office action of 1/26/05, and has been crossed out to avoid duplication upon printing of a patent or publication. Applicant is thanked for kindly supplying copies of references previously noted to be missing.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed 3/30/05 have been fully considered but they are not persuasive.

Claim 7 recites that "informative genes" may be selected from a list; however, the recited list comprises proteins. This claim was rejected in a previous office action as being indefinite as it was unclear whether applicant intended a gene or a protein. Applicant was reminded at that time that any amendment to the claims must be fully supported and enabled by the originally filed disclosure. The claim was amended to recite "genes encoding expression products" which new limitation was not supported by the specification. Now the claim has been amended to its original form and no longer recites new matter. However, as the list recited is NOT one of genes, it is again unclear what limitation applicant intends and the claim is again indefinite. In response to applicant's arguments, it is noted that "gene expression products" are defined as being proteins, peptides or nucleic acid molecules on page 21 of the specification; however, as "informative genes" are not defined to BE proteins, and those skilled in the art generally consider proteins and nucleic acids to be different biochemical molecules, the limitation of "informative genes" to be proteins is confusing, therefore the examiner maintains that the claim is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over ZHENG et al. IEEE Transactions on Neural Networks, (11/1997) vol. 8 (6), pp. 1386-1396) in view of EISEN et al. (IDS ref AV: PNAS (12/1998) vol. 95, pp. 14863-14868) and BARNHILL et al. (US 6,760,715, filed 5/1/1998).

Applicant's arguments with respect to claims 1-14 and 71 have been considered but are moot in view of the new ground(s) of rejection. It is noted that TAMAYO is no longer considered prior art in view of the declaration filed 3/30/05 pursuant to in re Katz.

ZHENG teaches a method of classifying malignant vs. benign breast tissue using weight adjustments (i.e. a weighted "voting" scheme), summation of votes and use of a

prediction threshold (confidence level) to determine a winning class (pp. 1389-1390).

ZHENG does not teach use of informative genes, classification of leukemia nor use of a statistical routine. ZHENG does not specifically teach a clustering routine.

EISEN teaches a method of clustering genes using a Euclidean routine to determine similarity (p. 14863). EISEN teaches that weighting may be used to order his genes (p. 14864), and teaches clustering of genes encoding many of the same proteins listed in instant claim 7 (Figure 2).

BARNHILL teaches analysis of gene expression patterns involved in various cancers using a linear discriminant classifier; i.e. weighted voting (col. 30, lines 47-col. 31, line 52) and clustering (col. 37, lines 52-61). BARNHILL teaches use of his SVM system to classify leukemia data, specifically to differentiate ALL from AML (col. 49, lines 27-37 and col. 50, line 51-col. 51, lines 1-20).

It would have been obvious to one of ordinary skill in the art to have combined ZHENG's weighted voting scheme, summation of votes, and confidence level threshold/cutoff with EISEN's Euclidean routines and/or BARNHILL's weighting and clustering routines to cluster and classify genes involved in cancer, specifically the leukemia of BARNHILL, where the motivation would have been to organize data in manner intuitive for biologists, as taught by EISEN (abstract) and to use a dataset and genes which provide a better performance for classification, as taught by BARNHILL (col. 51, lines 54-68). One skilled in the art would reasonably have expected success in combining the classification method of ZHENG with the classification of gene

Art Unit: 1631

expression data of EISEN and BARNHILL because all teach similar statistical methods of clustering and classification of biological/array data.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
4/13/05